

REMARKS

Claims 1 – 7, 9, and 10 are currently pending, with Claims 6, 7, 9, and 10 having been withdrawn from consideration and Claims 1 – 5 having been considered on the merits. In the Office Action, the Examiner rejected certain claims as allegedly lacking antecedent basis for certain limitations. Claims 1 – 5 were rejected under Section 112, first paragraph as allegedly failing to comply with the written description requirement. Claims 1 – 5 were also rejected under Section 103 as allegedly obvious over Miyazawa taken in combination with U.S. Patent No. 6,395,300 to Straub.

Each of the foregoing rejections is respectfully traversed. Favorable reconsideration is requested in view of the above amendments and following remarks.

I. The Antecedent Basis Objections.

The Examiner first contends that certain limitations in Claims 2 – 5 lack antecedent basis. In each instance, the alleged antecedent basis problem is said to stem from the recitation of “the DSC thermogram” (or “the IR spectrum” or “the X-ray powder diffractogram”) without a preceding recitation of “a DSC thermogram”, etc. In response, Applicant has amended each of Claims 2 – 4 to positively recite that the amorphous tamsulosin hydrochloride has “a DSC thermogram”, “an IR spectrum,” and/or “an X-ray powder diffractogram” in precedence to any later reference(s) to the same. In view of these amendments, it is respectfully requested that the antecedent basis objections be withdrawn.

II. The Written Description Rejections.

The Examiner also asserts that Claims 1 – 5 fail to satisfy the written description requirement. Specifically, the Examiner contends that, through a combination of melting points, differential scanning calorimetry (DSC) curves, infrared (IR) spectra, and X-ray diffractograms, the present disclosure characterizes and discloses only a single alleged “species” of amorphous tamsulosin hydrochloride. On the other hand, he asserts that the claims are directed to a much larger “genus” of what he says is an alleged “unlimited” number of amorphous tamsulosin hydrochloride “species.” According to the Examiner, since the so-called “genus” is much larger than the single “species” said to be described in the application, the written description requirement is not satisfied for the full scope of the claims

being sought.

It is respectfully submitted that the Examiner is mistaken in his position. Contrary to the contentions of the Examiner, there is no evidence of any “genus” of some unlimited number of “species” of amorphous tamsulosin hydrochloride. Instead, there is evidence of only one species, namely, amorphous tamsulosin hydrochloride.

In fact, this principal is applicable to any compound which exists in an amorphous form. While several different crystalline forms might exist for a morphic or polymorphic compound, there can really only be one amorphous (i.e., non-crystalline) form from the standpoint of meeting the definition of “amorphous” as understood by those of skill in the art. Amorphous means non-crystalline. Applicants are not aware of any compound which exhibits more than one amorphous state, and the Examiner has pointed to none either.

The present case only discloses and claims one amorphous form of tamsulosin hydrochloride, and it is clearly described and characterized in the specification. There is no valid basis to deem this to lack written description support vis-à-vis some imagined other “species.” Accordingly, it is submitted that the written description rejections are unfounded and should be withdrawn.

III. The Obviousness Rejections.

Finally, the Examiner contends that Claims 1 – 5 would have been obvious to a person of skill from Miyazawa combined with Straub. It is respectfully submitted that this rejection is not well taken and cannot be maintained.

Each of Claims 1 – 5 specifically recites tamsulosin hydrochloride in amorphous form. This is neither disclosed nor suggested by the cited references.

Admittedly, Miyazawa is directed broadly to tamsulosin hydrochloride; however, Miyazawa says nothing about an amorphous form of tamsulosin hydrochloride. The Examiner concedes as much.

Nonetheless, the Examiner asserts an amorphous form of tamsulosin would have been obvious from Straub since, in the Examiner’s view, Straub allegedly “discloses” a method for producing drugs in a crystalline state, an amorphous state, or mixtures thereof... wherein the drugs include tamsulosin hydrochloride.” However, Straub says nothing that can reasonably be said to suggest an amorphous form of tamsulosin. The Examiner significantly overstates the teachings of Straub.

Straub is generally directed to porous matrices said to provide enhanced dissolution of drugs. At columns 4 – 8, Straub lists scores of active ingredients which may be used in the practice of his technology and, at column 12, lines 42 – 45, Straub states that some of these drugs may be present in a crystalline form and some in an amorphous form. However, Straub says nothing whatsoever about the existence of tamsulosin hydrochloride in amorphous form.

Straub is akin to a broad statement to the effect that “some drugs might exist in crystalline form and some in amorphous form and some in both forms.” Such a generalized statement can hardly be said to foreclose patent protection for all subsequent developments that lead to various novel crystalline and/or amorphous forms of various pharmaceuticals as being “obvious;” any more than the first patent which mentioned the possibility of a light bulb which worked could be said to have made obvious Edison’s eventual development of one that did. It is well settled that broad disclosures of this sort do not foreclose patenting all later developments in the field as “obvious” under U.S. law. Otherwise, Straub should have been the last patent directed to an amorphous or crystalline form of any drug, and we should have a few thousand issued patents, at most, instead of millions. Our law is not as the Examiner supposes it to be.

Straub also plainly does not instruct those of skill in the art how to make tamsulosin hydrochloride in an amorphous form, i.e., it is a non-enabling reference for this purpose. “Although published subject matter is “prior art” for all that it discloses, in order to render an invention unpatentable for obviousness, the prior art must enable a person of ordinary skill to make and use the invention.” See *In re Kumar*, 418 F.3d 1361 (Fed. Cir. 2005).

Furthermore, even if Straub could somehow be said to hint at Applicant’s invention, and it does not, the fact remains that nothing whatsoever would have suggested any combination of Straub and Miyazawa that could have made Applicant’s claimed invention “obvious.” Nothing is shown to support any allegation that a person of skill would have any motivation at all to combine these references to even attempt to make what Applicant is claiming, much less any way to do so. The references are not “obviously” combinable in regard to Applicant’s claimed invention, but even considered together, they cannot objectively be said to suggest the same.

In view of at least the above deficiencies, it is submitted that the obviousness rejections based on the purported combination of over Miyazawa with Straub cannot stand and should be withdrawn.

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In light of the foregoing, Applicants urge the Examiner to reconsider the application, to withdraw the rejections, and to issue a notice of allowance at the earliest possible convenience.

In the event this response is not timely filed, Applicant hereby petitions for the appropriate extension of time and requests that the fee for the extension along with any other fees which may be due with respect to this paper be charged to our **Deposit Account No. 12-2355**.

Respectfully submitted,

By: /Mark S. Graham/

Mark S. Graham

Registration No. 32,355

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P.O. Box 1871
Knoxville, Tennessee 37901
865-546-4305